16m4 3/5/41

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

W. CO

In re application of

Carney et al

Examiner D.C. Jones

Serial No. 08/962,040

Art Unit 1205 1614

Filed: October 31, 1997

For: Spin-Trapping Pharmaceutical Compositions

and Methods of Use Thereof

RECEIVED

## INFORMATION DISCLOSURE STATEMENT

FEB 2 7 1998

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

MATRIX CUSTOMER SERVICE CENTER

Sir:

Applicants submit herewith the following documents for consideration in connection with the examination of the above application:

- (1) U.S. Patent No. 4,153,722 (Campbell et al)
- (2) U.S. Patent No. 4,197,314 (Campbell et al)
- (3) U.S. Patent No. 4,214,003 (Campbell et al)
- (4) U.S. Patent No. 4,224,340 (Campbell et al)
- (5) U.S. Patent No. 5,352,442 (Proctor)
- (6) U.S. Patent No. 5,472,687 (Proctor)
- (7) U.S. Patent No. 5,569,663 (Ribier et al)
- (8) U.S. Patent No. 5,679,691 (Ribier et al)
- (9) EP 327,263 (Proctor)
- (10) WO 88/05653 (Proctor)
- (11) Proctor U.S. Patent application Serial No. 149,720, filed January 29, 1988

The '722, '314, '003 and '340 patents are each directed to the topical administration of alpha-phenyl-N-phenylnitrones for the treatment of inflammation. The patents are silent as to the treatment of radiation-induced injury.

The '442 patent is directed to the use of the spin trap compound TEMPO in a topical formulation to treat hair loss as well as to stimulate hair growth. The patent teaches as column 2, lines 26-42 that the hair loss may be due to chemotherapy or radiation treatment. No spin trap compounds other than TEMPO are disclosed. The patent claims priority of application Serial No. 149,720, filed January 29, 1988 (now abandoned), which provides support for the claimed invention with the exception of the use of the topical TEMPO composition to treat radiation-induced hair loss (the 149,720 application is silent with regard to radiation injury). The effective date of the "radiation-injury" embodiment of the '442 patent is thus February 24, 1993, which is subsequent to the June 18, 1991 effective date for which we will attempt to claim priority. A copy of application Serial No. 149,720 is attached for review by the Examiner.

The '687 patent discloses topical POBN compositions for the treatment of hair loss or stimulation of hair growth. The patent teaches that hair loss may be due to chemotherapy or radiation-treatment. This patent claims priority through the '442 patent discussed above. However, the '442 patent does not provide support for a POBN composition. The effective date of this patent thus appears to be the filing date of February 7, 1994.

The '663 and '691 patents disclose a cosmetic or dermatological topical skin composition which comprises a spin trap compound such as PBN or TEMPO. A method of treatment of the skin by use of such a compound is claimed in the '691 patent (see

claim 1 of the patent). The effective date of these patents is subsequent to the priority date claimed by applicants in the instant application.

EP 327,263 published on August 9, 1989. This application claims priority of U.S. patent application Serial No. 149,720. The EP publication discloses topical hair growth compositions which may include a spin trap compound alone (such as PBN) with a topical carrier. This publication is silent with regard to the treatment of radiation injury.

The WO 88/05653 publication discloses a topical composition for treatment of hair loss which may contain a spin trap such as PBN. This publication has a publication date of August 11, 1988. The teachings of this publication require the use of other active ingredients in addition to the spin trap compound. This publication is <u>silent</u> with regard to the treatment of radiationinduced injury.

Respectfully submitted,

BY:

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